

with new nonporous material. All tracks and belts that come into contact with the can seams should be thoroughly scrubbed and sanitized at intervals of sufficient frequency to avoid product contamination.

### Subpart E—Production and Process Controls

#### § 113.81 Product preparation.

(a) Before using raw materials and ingredients susceptible to microbiological contamination, the processor shall ensure that those materials and ingredients are suitable for use in processing low-acid food. Compliance with this requirement may be accomplished by receiving the raw materials and ingredients under a supplier's guarantee that they are suitable for use, by examining them for their microbiological condition, or by other acceptable means.

(b) Blanching by heat, when required in the preparation of food for canning, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent processing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by cleaning. If the blanched food product is washed before filling, potable water should be used.

(c) The filling of containers, either mechanically or by hand, shall be controlled so as to ensure that the filling requirements specified in the scheduled process are met.

(d) The exhausting of containers for the removal of air shall be controlled so as to meet the conditions for which the process was designed. Compliance with the requirement may be accomplished by heat exhausting, mechanical exhausting, hot brining, or steam injection.

(e) When the maintenance of pH (above 4.6) of a normally low-acid food is a basis for a scheduled process, there shall be careful supervision to ensure that the equilibrium pH of the finished product meets that of the scheduled process. The methodology described in § 114.90 of this chapter should be used.

(f) When the scheduled process sets forth critical factors to prevent the growth of microorganisms not destroyed by the thermal process, the factors shall be carefully controlled to ensure that the limits established in the scheduled process are not exceeded. When normally low-acid foods require sufficient solute to permit safe processing at low temperatures, such as in boiling water, there shall be careful supervision to ensure that the equilibrium water activity ( $a_w$ ) of the finished product meets that of the scheduled process. The scheduled thermal processes for foods having an  $a_w$  greater than 0.85 and less than the  $a_w$  that would allow the growth of spores of microorganisms of public health significance shall be sufficient to render the food free of microorganisms capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution.

#### § 113.83 Establishing scheduled processes.

Scheduled processes for low-acid foods shall be established by qualified persons having expert knowledge of thermal processing requirements for low-acid foods in hermetically sealed containers and having adequate facilities for making such determinations. The type, range, and combination of variations encountered in commercial production shall be adequately provided for in establishing the scheduled process. Critical factors, e.g., minimum headspace, consistency, maximum fill-in or drained weight,  $a_w$ , etc., that may affect the scheduled process, shall be specified in the scheduled process. Acceptable scientific methods of establishing heat sterilization processes shall include, when necessary, but shall not be limited to, microbial thermal death time data, process calculations based on product heat penetration data, and inoculated packs. Calculation shall be performed according to procedures recognized by competent processing authorities. If incubation tests are necessary for process confirmation, they shall include containers from test trials and from actual commercial production runs during the period of instituting the process. The incubation tests for confirmation of the scheduled